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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,656	04/08/2004	David K. Gong	31176282-004001	8010

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/820,656	**Applicant(s)** GONG ET AL.	
	Examiner James H. Alstrum-Acevedo	**Art Unit** 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *29,32,33,36,37 and 40*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

    _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s): _____
13. ☒ Other: See Continuation Sheet.

JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1600

Continuation of 5. Applicant's reply has overcome the following rejection(s): 112, 1st paragraph (new mattter) of claims 32 and 36; 112, 2nd paragraph of claims 29, 32-33, 36, and 40.

Continuation of 13. Other: Applicants' amendments have removed the new matter in claims 32 and 36. The Examiner acknowledges Applicants various reference citations in footnote 1 of their remarks, which demonstrate that the step of "slowly, maximally inhaling" is both well known and conventionally practiced in the field of inhalable pharmaceutical formulations. Because the step of "slowly, maximally inhaling" is conventional and well known, as evidenced by Applicants comments and various reference citations, it is unnecessary to cite any additional references in the rejections under §103(a), as this step would be readily known to any ordinary skilled artisan at the time of the instant invention with regards to the inhalation administration of any pharmaceutical formulation. Applicants' arguments traversing the art rejections, all of which are based on the "Lechuga" reference, are unpersuasive. Applicants have argued that the Examiner has argued inherency concerning the absence of ethanol in the prior art formulations, which is incorrect. The dry powders made by Lechuga were made by spray dryng aqueous formulations. None of the Examples in Lechuga utilize formulations comprising ethanol in the spray drying process. Thus, it is proper to conclude that the Lechuga Factor IX (FIX) dry powders contain no ethanol. Lechuga's dry powders are also taught as preferably having a water content below 10%. Applicants have argued the showing of alleged unexpected results by presenting alleged comparative data that compares Applicants' results with Gupta (intravenously injectable FIX solutions). Gupta was not cited in any rejection, thus this comparison is off point. The closest prior art is Lechuga not Gupta. Furthermore, for a showing of unexpected results to be convincing it must be commensurate in scope with what is claimed. Applicants data are for compositions comprising specific amounts of FIX, sodium citrate, and leucine. Allegations of unexpected results based upon the administration of formulations that do not explicitly comprise the same components as the formulations for which Applicants have data are unpersuasive on their face. Applicants have argued that Lechuga's inhalable FIX dry powders lack the required physical and physiological properties recited in Applicants claims. The Examiner respectfully disagrees. Lechuga's FIX dry powders are characterized by an MMAD of 2.7 microns and an emitted dose of 89%, which meet the required aerodynamic properties of the FIX powders administered in Applicants' methods. FIX is a protein that consists of a single polypeptide (i.e. it is monomeric). Thus, there is no reason to believe the FIX in Lechuga's invented inhalable powders is not monomeric. Applicants have not provided any data to demonstrate that the Lechuga FIX dry powders comprise non-monomeric FIX. Regarding the step of "allowing said monomeric FIX to deposit in the deep lung tissue", this step does not need to be explicitly disclosed, because upon inhalation of, for example, Lechuga's FIX dry powders with a MMAD of 2.7 microns these powders will passively settle in the deep lungs of the patient inhaling the powder. It is long established and well known in the art the correlation between an inhalable powder's given particle size and its final destination in the lungs upon inhalation (see, for example, Radhakrishan (U.S. Patent No. 5,192,528)). Regarding the physiological effects claimed in Applicants' methods, because the inhalable FIX powders invented by Lechuga are substantially similar to those invented, but not recited in Applicants' claims, the recited physiological properties must necessarily also result from the inhalation of Lechuga's FIX dry powders. Applicants have not provided any data to demonstrate otherwise. Thus, the rejections under §103(a) are proper and are maintained.